



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2015-0561; FRL-9949-19]

Flonicamid; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of flonicamid in or on hops, tree nuts (crop group 14-12 except pistachio), and pistachio. ISK Biosciences Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the **Federal Register***].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the **Federal Register***], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the

SUPPLEMENTARY INFORMATION).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2015-0561, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday,

excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Susan T. Lewis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: *RDFRNotices@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2015-0561 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2015-0561, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of October 21, 2015 (80 FR 63731) (FRL-9935-29), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 5F8369) by ISK Biosciences Corporation, 7470 Auburn Road, Suite A, Concord, Ohio, 44077. The petition requested that 40 CFR 180.613 be amended by establishing tolerances for residues of the insecticide flonicamid, [(N-(cyanomethyl)-4-trifluoromethyl)-3-pyridinecarboxamide) or (N-cyanomethyl-4-trifluoromethylnicotinamide (IUPAC))], in or on hops at 20 parts per million (ppm), tree nuts (crop group 14-12) except pistachio at 0.15 parts per million (ppm), pistachio at 0.60 parts per million (ppm). That document referenced a summary of the petition prepared by ISK Bioscience Corporation, the registrant, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the

tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for flonicamid including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with flonicamid follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by flonicamid as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are

discussed in the final rule published in the **Federal Register** of November 14, 2012 (77 FR 67771) (FRL-9368-7).

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which the NOAEL and the LOAEL are identified. Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see

<http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for flonicamid used for human risk assessment is discussed in Unit III.B of the final rule published in the **Federal Register** of November 14, 2012.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to flonicamid, EPA considered exposure under the petitioned-for tolerances as well as all existing flonicamid tolerances in 40 CFR 180.613. EPA assessed dietary exposures from flonicamid in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. No such effects were identified in the toxicological studies for flonicamid; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA's National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). As to residue levels in food, the chronic dietary exposure assessment was a conservative assessment conducted using tolerance-level residues, conservative ground water/drinking water estimates, and 100 percent crop treated (PCT).

iii. *Cancer.* Based on the data referenced in Unit III.A., EPA has concluded that flonicamid does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and PCT information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for flonicamid. Tolerance level residues and/or 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for flonicamid in

drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of flonicamid. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

The drinking water assessment was conducted using both a parent only exposure, and a total toxic residue approach, which considers the parent compound and its major degradates of concern. Total toxic residues include 4-trifluoromethylnicotinic acid (TFNA), 4-trifluoromethylnictinamide (TFNA-AM), 6-hydro-4-trifluoromethylnicotinic acid (TFNA-OH), *N*-(4-trifluoromethylnicotinoyl)glycine (TFNG), and *N*-(4-trifluoromethylnicotinoyl)glycinamide (TFNG-AM).

Based on the Pesticide Root Zone Model Ground Water (PRZM GW), the estimated drinking water concentrations (EDWCs) of flonicamid for chronic exposures for non-cancer assessments are estimated to be 0.94 parts per billion (ppb) for surface water and 9.92 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the water concentration of value 9.92 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Flonicamid is not registered for any specific use patterns that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity.*

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.” EPA has not found flonicamid to share a common mechanism of toxicity with any other substances, and flonicamid does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that flonicamid does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at

<http://www.epa.gov/pesticides/cumulative>.

D. *Safety Factor for Infants and Children*

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor (FQPA SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* The prenatal and postnatal toxicity database for flonicamid includes prenatal developmental toxicity studies in rats and rabbits and a multi-generation reproduction toxicity study in rats. There is no evidence of increased susceptibility (qualitative or quantitative) in rats or rabbits exposed to flonicamid *in utero* in the prenatal developmental studies or in young rats in the multi-generation reproduction study. No developmental effects were seen in rabbits. In the multi-generation reproduction study, developmental delays in the offspring (decreased body weights, delayed sexual maturation) were seen only in the presence of parental toxicity (kidney and blood effects). Also, there are clear NOAELs and LOAELs for all effects. The degree of concern for prenatal and/or postnatal susceptibility is, therefore, low due to the lack of evidence of qualitative and quantitative susceptibility.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X, except as noted below. That decision is based on the following findings:

i. The toxicity database for flonicamid is nearly complete. The database is missing a subchronic inhalation study. A subchronic inhalation study is required because the use of an oral POD results in MOEs which do not meet the target MOE for a waiver (MOE=1,000). The Agency notified the registrant of the Data Call-In (DCI) for the 28-day inhalation study on January 5, 2016 and is awaiting submission of the study. In the absence of a subchronic inhalation study, EPA has retained a 10X FQPA SF to assess risks for inhalation exposure scenarios. However, residential inhalation exposures are not expected.

ii. The available data base for flonicamid includes acute and subchronic neurotoxicity studies. As discussed in Unit III.A., EPA has concluded that the clinical signs observed in those studies were not the result of a neurotoxic mechanism and therefore a developmental neurotoxicity study is not required.

iii. There is no evidence that flonicamid results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The chronic dietary food exposure assessment was based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to flonicamid in drinking water. These assessments will not underestimate the exposure and risks posed by flonicamid.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, flonicamid is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to flonicamid from food and water will utilize 30% of the cPAD for children 1-2 years old, the population group receiving the greatest exposure. There are no residential uses for flonicamid. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of flonicamid is not expected.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). A short-term adverse effect was identified; however, flonicamid is not registered for any use patterns that would result in short-term residential exposure. Short-term risk is assessed based on short-term residential exposure plus chronic dietary exposure. Because there is no short-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short-term risk), no further assessment of short-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short-term risk for flonicamid.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). An intermediate-term adverse effect was identified; however, flonicamid is not registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been

assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for flonicamid.

5. *Aggregate cancer risk for U.S. population.* Based on the information referenced in Unit III.A., EPA has concluded that the cPAD is protective of possible cancer effects from flonicamid, and as evidenced in Unit III.E.2, aggregate exposure to flonicamid is below the cPAD.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to flonicamid residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (FMC Method No. P-3561M, a liquid chromatography with tandem mass spectrometry (LC/MS/MS) method) is available to enforce the tolerance expression for flonicamid and its metabolites in or on plant commodities.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and

agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not proposed an MRL for flonicamid in or on pistachio. The Codex has established an MRL for flonicamid in or on hops at 20.0 ppm. These MRLs are the same as the tolerances established for flonicamid in the United States. The Codex has also established MRLs for flonicamid in or on almond and pecan at 0.01 ppm. These MRLs are different than the tolerances established for flonicamid in the United States. The U.S. cannot harmonize the Nut, tree, group 14-12, except pistachio tolerance with the Codex MRLs on pecan and almond because residue field trial data show residues well above 0.01 ppm.

C. Revisions to Petitioned-For Tolerances

The Agency is removing certain commodities from the table at § 180.613 (a) to eliminate redundancies upon the establishment of new crop group tolerances that were not identified in the petition: Cucumber at 1.5 ppm and okra at 0.40 ppm.

V. Conclusion

Therefore, tolerances are established for residues of flonicamid, [(N-(cyanomethyl)-4-trifluoromethyl)-3-pyridinecarboxamide) or (N-cyanomethyl-4-

trifluoromethylnicotinamide (IUPAC)]], in or on hops at 20.0 ppm, tree nuts (crop group 14-12) except pistachio at 0.15 ppm, and pistachio at 0.60 ppm.

Also, as a housekeeping measure, the Agency is removing three individual tolerances that are subsumed within other crop group tolerances contained in §180.613: Cucumber at 1.5 ppm is superseded by inclusion in the established vegetable, cucurbit, group 9 tolerance at 1.5 ppm; and okra at 0.40 ppm is superseded by inclusion in the established vegetable, fruiting, group 8-10 tolerance at 0.40 ppm.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the

issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to

publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: July 26, 2016.

Daniel J. Rosenblatt,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In § 180.613, amend the table in paragraph (a)(1) as follows:

- a. Remove the commodities “Cucumber” and “Okra”.
- b. Revise the commodities “Hop, dried cones” and “Nut, Tree, group 14-12”.
- c. Add alphabetically the commodity “Pistachio”.

The revisions and addition read as follows:

§ 180.613 Flonicamid; tolerances for residues.

(a) * * *

(1) * * *

Commodity	Parts per million

Hop, dried cones	20.0
Nut, Tree, group 14-12 except pistachio	0.15

Pistachio	0.60

* * * * *

[FR Doc. 2016-18666 Filed: 8/5/2016 8:45 am; Publication Date: 8/8/2016]